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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,324

12/20/2004

Zicai Liang

040679

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EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

01/10/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,324	LIANG ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12, 16, 17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on November 22, 2010.

Currently, claims 1-8, 10, and 12-20 are pending in the instant application. Claims 13-15 and 18-19 have been withdrawn from further consideration as being drawn to non-elected inventions. Accordingly, claims 1-8, 10, 12, 16-17, and 20 are under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Priority

The denial of granting the provisional application filing date remains effective for the reasons of record as set forth in the Office action mailed on July 22, 2010 and for the reasons stated below.

It is noted that applicant has not provided any rebuttal arguments addressing the priority issues, nor has applicant particularly pointed out where the adequate support can be found in 60/390,108. Hence, the effective filing date for claims 1-8, 10, 12, 16-17, and 20 remains as the filing date of PCT/SE2003/001077.

Claim Rejections - 35 USC § 112

Claims 1-8, 10, 12, and 16-17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as set forth in the Office action mailed on July 22, 2010 and for the reasons stated below.

Applicant's arguments filed on November 22, 2010 have been fully considered but they are not persuasive. Applicant argues that the subject matter, a "library" of dsDNA molecules, claimed in the instant case is fully supported by the disclosure of the instant specification. In so arguing, applicant asserts that since the claims are drawn to the "library", not a single dsRNA shorter than 19 base pairs, the fact that some dsRNAs shorter than 19 base pairs are "not useful in one particular application" does not support that the claimed "library" is not adequately described in the specification. It is noted that applicant's line of reasoning is self-contradictory and is based on a partial claim interpretation or partial reading of the claims. It is true that the claims are drawn to a "library" as evidenced by the preamble language. However, the claims do require that the "library" produce a plurality of dsRNAs of "predefined" lengths ranging from 10 to 30 base pairs "encoding the dsRNA to be produced". Hence, although the preamble recites a "library", the claims as a whole are drawn to a collection of dsRNAs of different lengths, wherein the dsRNA produced by the "library" are 10-30 base pairs. Now, as noted in the last Office action, the instant specification makes it clear that the "library" that "produces" dsRNAs is

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for producing those dsRNAs that mediate RNA interference. Hence, the claimed library in the instant case should produce dsRNAs that mediate RNAi as described in the specification and as intended by the inventors. However, as noted in the last Office action, the inventors themselves expressly acknowledged in the specification that dsRNAs that mediated RNAi are 19-21 base pairs in length. As such, the specification, at best, describes that there is a structure/function correlation for a library that produces dsRNAs of predefined lengths of about 19-21 base pairs only. Hence, the claimed library that produces dsRNAs that are 10 base pairs or 30 base pairs is not whatsoever adequately described as alleged by applicant, nor does the specification support the fact that the inventors were in possession of the genus claimed in the instant case at the time of filing. Note that even the "drawings" (see Figure 1) depict "a DNA library that can encode all double stranded RNA with 19 base pair duplex" (emphasis added). See page 3. In fact, the specification shows a construction of a library wherein "All sequenced clones contain the expected 19 base pair insert as expected." (emphasis added). See page 8. Further, the specification shows a construction of randomized DNA library having "19, 20 and 21 nt of randomized region embedded within the two known sequences." (see page 7), thus supporting the art-recognized fact that the duplex siRNAs that mediated RNAi are 19-21 base pairs. Furthermore, with regard to making a library that encodes dsRNAs of different lengths from 10 to 30 base pairs, the specification is entirely prophetic: "The same procedure can be used to produce such DNA libraries encoding different length (10-30 base pair) of double stranded RNA" (emphasis added). See page 3. That is, except for the mere disclosure of such prophetic statements, there is no evidence showing that the inventors actually made a library producing varied lengths of dsRNAs that mediated RNAi contrary to the art-accepted knowledge that RNAi activity is highly dependent on the dsRNA lengths. Furthermore, the inventors themselves warn

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about the criticality of the length of dsRNAs for RNAi activity or for the utility of the library itself. See page 4: “the libraries of the invention have been restricted to double stranded DNA and RNA of a length of 10-30 base pairs, since above the length of 30 base pairs, the nucleotides will be more likely to produce an immunoresponse, and other disturbing side-effects when transfected into living cells.” Again, the disclosure of the specification makes it very clear that the inventors failed to demonstrate, contrary to the conventional knowledge pertaining to the relationship between siRNA lengths and RNAi activity, that a dsRNA of 10 base pairs or 30 base pairs produced by the claimed library have the intended functionality. Again, the actual construction of a library that produces “all” 19 base pairs or 19-21 base pairs is not a representative number of species encompassed by the broad genus claimed in the instant case. Is applicant arguing that the claimed library that produces only non-functional siRNAs (e.g., a library that only produces dsRNA of 10 base pairs as claimed and fully encompassed by the claims) is adequately supported by the disclosure of the instant specification? Again, note that neither the specification nor the state of the art at the time of filing teaches that a dsRNA of 10 base pairs is capable of being an siRNA that mediates RNAi in cells.

For some unclear reason, applicant states that the claimed library also contains a promoter sequence and a terminator sequence and alleges that the examiner has not addressed the other sequences in the library. Again, applicant's attention is directed to the claim language constructed by applicant himself/herself. Note that the specific length limitation written by applicant only applies to the dsRNA. For example, see "a dsRNA-encoding sequence of 10-30 base pairs encoding the dsRNA produced". Hence, given the applicant's own construction of the claim language which only focuses on the dsRNA for length limitation, wherein such length limitation is found to have no structure/function correlation or actual reduction to practice as

noted in the last Office action, the examiner does not understand why the other sequences (promoter, terminator) should be addressed for the lack of written description requirement for the claims that require specific lengths only for the dsRNA, which should have RNAi functionality as described and intended by the disclosure of the instant specification. Hence, the examiner finds applicant's arguments irrelevant and out of scope.

Since applicant's arguments are not persuasive or convincing at all, this rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 1-8, 10, 12, 16-17, and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. for the reasons of record as set forth in the Office action mailed on July 22, 2010 and for the reasons stated below.

Applicant's arguments filed on November 22, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated by Li et al. because the Li et al. reference does not qualify as prior art. In so arguing, applicant asserts that the examiner did not provide a copy of the provisional application of the Li et al. reference and that applicant does not have a copy of the provisional application of the Li et al. reference. Applicant's attention is directed to the fact that there is no requirement for the examiner to provide a copy of a provisional application of a cited patent application publication. Hence, the examiner does not understand applicant's demand that "a copy of this application should be provided" and applicant's demand that "the content of this application [60/398,915] should be specifically cited in the rejection." Applicant is advised to point out a rule in MPEP, which shows that it is examiner's duties to provide a copy of a provisional application and to specifically cite the

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provisional application when a 102(e) prior art reference is cited and that applicant's demands are thus justified. Further, the mere fact that applicant does not know how to obtain a copy of a provisional application of another patent application does not whatsoever indicate that the instant rejection is "improper" as alleged by applicant. That is, applicant has failed to demonstrate that the Li et al. reference is not supported by its provisional application filed on July 24, 2002, nor has applicant demonstrated that the Li et al. reference fails to teach the claimed subject matter. Further, for applicant's own edification, applicant is advised to access the PAIR (Patent Application Information Retrieval) system or contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free) or e-mail EBC@uspto.gov for obtaining a copy of 60/398,915. Since applicant's arguments are not persuasive at all, this rejection is maintained.

Conclusion

No claim is allowed.

This application contains claims 13-15 and 18-19 drawn to inventions nonelected with traverse in the reply filed on May 26, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita (AU1637, Acting SPE) can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1635

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Primary Examiner, Art Unit 1635